

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1. (currently amended): A once a day pharmaceutical dosage form comprising an extended release formulation of the water-soluble drug substance Venlafaxine HCl, comprising a hard gelatin capsule containing a therapeutically effective number of mini tablets, wherein each mini-tablet comprises ~~comprising of~~ a functional core and a functional coating layer or a functional coating film, and wherein the functional core is produced with compression technology and comprises an extended release formulation of the water-soluble drug substance Venlafaxine HCl and wherein the functional coating layer or functional coating film coats the functional core and limits the initial rapid diffusion of the water-soluble drug substance from the functional cores.

2. (currently amended): A pharmaceutical dosage form according to claim 1 wherein the cores of the mini tablets ~~are composed of about~~ comprises 10-40% by weight of Venlafaxine HCl, ~~about~~ 40-80% by weight of a gelling agent, ~~about~~ 30-60% by weight of a non-swelling agent, 2-12% by weight of a conjugation agent and 1-30% by weight of classical excipients with the exception of excipients that exhibit disintegrating properties.

3. (currently amended): A pharmaceutical dosage form according to claim 2 wherein the gelling agent ~~is comprises a polymer is selected from the group of and wherein said polymer comprises one of~~ Hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxycellulose phthalate, poly(ethyleneoxide), polylactic acid, xanthan gum, alginates, sodium and calcium carboxymethylcellulose, carrageen, carbomer, carbopol, ~~(oral use), methylhydroxyethylcellulose, propylhydroxyethylcellulose, polyhema, methylcellulose or and alginates.~~

4. (currently amended): A pharmaceutical dosage form according to claim 2-3 wherein

the non-swelling agent comprises a polymer and wherein said polymer comprise one of is ~~selected from the group comprising from~~ ethyl cellulose, cellulose acetate propionate, cellulose acetate, poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride) 1:2:0.1, commerced as Eudragit RS 100, poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride) 1:2:0.2 copolymer, commercially available as Eudragit RL.RTM., polyvinylpyrrolidone acetate, polyvinyl chloride, polyvinyl acetate or polyethylene.

5. (currently amended): A pharmaceutical dosage form according to claim ~~2-4~~ wherein the polymers of the core are conjugated by a pharmaceutically accepted conjugation agent, ~~such as and~~ wherein said conjugation agent comprises one of sodium lauryl sulphate, sodium docusate, sodium cetostearyl sulphate or and ~~triethanolamine lauryl sulphate~~, that causes the decrease on the swelling properties of the core.

6. (currently amended): A pharmaceutical dosage form as defined in claim 1 wherein the cores ~~are is~~ partially coated by a the functional coating layer, and wherein the functional coating layer covers eovering one or two surfaces of the core, or one surface and the perimeter of the core and the thickness of the coating layer ranges ranging between 3-30% of the diameter of the core.

7. (currently amended): A pharmaceutical dosage form as defined in claim 6, wherein the functional coating layer is comprised of a polymer and a water soluble compound, wherein ~~the said polymer and the said water soluble compound~~ are present in a weight ratio of about 1:1 to 9:1.

8. (currently amended): A pharmaceutical dosage form as defined in claim ~~7~~6, wherein the polymer of the functional coating layer ~~is either selected from the group consisting of~~ comprises one of swellable polymers ~~as the ones recited above in claim 3, or from the group consisting of non-swellable polymers, as the ones recited above in claim 4 ; and~~ wherein the swellable polymers comprise one of Hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxycellulose phthalate, poly(ethyleneoxide), polylactic acid,

xanthan gum, alginates, sodium and calcium carboxymethylcellulose, carrageen, carbomer, carbopol, methylhydroxyethylcellulose, propylhydroxyethylcellulose, polyhema, methylcellulose or alginates; and
wherein the non-swellaable polymers comprise one of ethyl cellulose, cellulose acetate propionate, cellulose acetate, poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride) 1:2:0.1, commercered as Eudragit RS 100, poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride) 1:2:0.2 copolymer, commercially available as Eudragit RL.RTM., polyvinylpyrrolidone acetate, polyvinyl chloride, polyvinyl acetate or polyethylene.

9. (currently amended): A pharmaceutical dosage form as defined in claim 67, wherein the water soluble compound of the functional coating layer is selected either from the group of comprises one of water soluble salts, such as sodium chloride, sodium bicarbonate or ~~the group of~~ low relative molecular mass organic solid excipients, such as mannitol, lactose, sucrose, sorbitol, ~~or citric acid or from the group of~~ water soluble polymers such as polyvinylpyrrolidone, polyvinyl alcohol or low viscosity hydroxypropylmethyl cellulose.

10. (currently amended): A pharmaceutical dosage form as defined in claim 1 wherein the ~~cores are film coated by a functional coating film, that represents about 1.5 to 18% by weight of the weight of the core, and is applied to a sufficient thickness to reduce the initial release of the drug substance from the said formulation.~~

11. (currently amended): A pharmaceutical dosage form as defined in claim 10, wherein the functional coating film is comprised of a polymer in a proportion of 10-80% of ~~the a~~ dry coating material and a water soluble compound, in a proportion of 20-50% of the dry coating material.

12. (currently amended): A pharmaceutical dosage form as defined in claim 11, wherein the polymer of the functional coating film comprises one of ~~is selected either from the group consisting of swellaable polymers such as the ones recited in claim 3, or from the~~

~~group consisting of non-swellable polymers such as the ones recited in claim 4 or from the group of pH-depended polymers that are insoluble in acidic environments while they soften or dissolve in neutral or basic environments;~~ and
wherein said pH-depended polymers such as comprise one of cellulose acetate phthalate, Poly(butyl methacrylate, (2-dimethyl aminoethyl) methacrylate, methyl methacrylate) 1:2:1 copolymer, commercially available as Eudragit E.RTM., poly(ethyl acrylate, methyl methacrylate) 2:1 copolymer, commercially available as Eudragit 30D.RTM., poly(methacrylic acid, methyl methacrylate) 1:1 copolymer, commercially available as Eudragit L.RTM., or poly(methacrylic acid, methyl methacrylate) 1:2 copolymer, commercially available as Eudragit S.RTM..

13. (currently amended): A pharmaceutical dosage form as defined in claim 11, wherein the water-soluble compound of the functional coating film comprises one of water soluble salts, such as sodium chloride, sodium bicarbonate or low relative molecular mass organic solid excipients, such as mannitol, lactose, sucrose, sorbitol or citric acid or water soluble polymers such as polyvinylpyrrolidone, polyvinyl alcohol or low viscosity hydroxypropylmethyl cellulose is selected from the groups recited above in claim 9.

14. (currently amended): A pharmaceutical dosage form as defined in claim 1 wherein the functional coating layer or the functional coating film further comprises a pharmaceutically accepted plasticizer.

15. (currently amended): A pharmaceutical dosage form as defined in claim 1 wherein the functional coating layer further comprises classical excipients selected from the group of binders, diluents, glidants, lubricants, adhesive agents, opacifiers ~~and~~ or colourants.

16. (currently amended): A pharmaceutical dosage form as defined in claim 1 wherein the functional coating film further comprises classical excipients selected from the groups of ~~and~~ colourants.

17. (currently amended): A pharmaceutical dosage form as defined in claim 11 wherein

the functional coating film is applied from a solution or dispersion of ~~the~~-said polymer and ~~the~~-said water soluble compound in a pharmaceutically acceptable solvent or mixture of pharmaceutically acceptable solvents where the selected constituents of the coating film can be uniformly dissolved or dispersed.

18. (currently amended): A pharmaceutical dosage form as defined in claim ~~1~~-2, wherein the drug substance, the gelling agent, the non-swellable ~~polymer~~-ing agent and the conjugation agent are wet granulated using a pharmaceutically acceptable solvent or mixture of solvents.

19. (currently amended): A pharmaceutical dosage form as defined in claim 1, wherein ~~the~~-said capsule comprises one to six of ~~the~~-said mini tablets each ~~one~~-tablet containing 25 to 75 mg of the drug substance.

20. (currently amended): A pharmaceutical dosage form as defined in claim 1, wherein linearity between the total weight of ~~the~~-said mini tablets and the strength of ~~the~~-said dosage form is achieved.

21. (currently amended): A pharmaceutical dosage form as defined in claim 1, wherein the dose ~~may be~~is divided by reducing the number of tablets in each capsule.

22. (original): A pharmaceutical dosage form as defined in claim 1, comprising an extended release formulation for once daily administration, which comprises mini tablets partially or totally coated by a coating layer or coating film that is functional only during the first 2-4 hours of the drug release.

23. (currently amended): A method of preparing a drug delivery system for Venlafaxine which comprises: a) preparing mini-tablets ~~the cores containing Venlafaxine HCl according to claim 5~~ by a wet granulation, drying and compression process, wherein each mini-tablet comprises a core containing an extended release formulation of water-soluble Venlafaxine HCl b) applying a functional coating layer on each of the cores, ~~according to~~

~~claim 9~~, using a direct compression process or applying a functional coating film on each
of the cores using a spraying process, c) encapsulating the prepared mini tablets by using
an appropriate encapsulating device; and

wherein the functional cores are conjugated by a pharmaceutically accepted conjugation
agent, such as sodium lauryl sulphate, sodium docusate, sodium cetostearyl sulphate or
triethanolamine lauryl sulphate, that causes the decrease on the swelling properties of the
core; and

wherein the functional coating layer is comprised of a polymer and a water soluble
compound and wherein the water soluble compound comprises one of water soluble
salts, such as sodium chloride, sodium bicarbonate or low relative molecular mass
organic solid excipients, such as mannitol, lactose, sucrose, sorbitol or citric acid or water
soluble polymers such as polyvinylpyrrolidone, polyvinyl alcohol or low viscosity
hydroxypropylmethyl cellulose.